

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0021/078/002

Case No: 2032044

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Bayer PLC

Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Rennie Rap-eze Orange Flavour 500mg Chewable Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **24/05/2007**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Rap-Eze Orange Flavour 500mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg calcium carbonate.
Also contains 887.5 mg sucrose and 1.5 mg ponceau 4R (E124).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet

Orange coloured square tablets with rounded corners and bevelled edges with an orange odour and flavour. Both faces are concave and impressed with the word 'RENNIE' on one face and 'RAP-EZE' on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of stomach upset due to hyperacidity and heartburn, e.g. indigestion, hyperacidity, flatulence, dyspepsia, biliousness, and acid indigestion.

4.2 Posology and method of administration

Tablets to be taken orally, sucked or chewed according to the following dosage schedules.

Adults: One or two tablets to be sucked or chewed as required, to a maximum of sixteen tablets a day.

Elderly persons: No special dosage regimen is required, but care should be taken to observe the contraindications and warnings.

Children: Not recommended for children under 12.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may impair the absorption of other drugs, including antibiotics and tetracyclines if taken concomitantly. If the user is taking other prescribed medicines, professional advice should be sought before taking this product.

4.6 Pregnancy and lactation

Epidemiological studies show no increase in teratogenic and other hazards to the foetus if used at the recommended dose during pregnancy.

May be taken during pregnancy or during lactation, but as with all medicines it should only be taken during pregnancy or during lactation when considered necessary.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No side effects have been reported at the recommended dose.

4.9 Overdose

Milk alkali syndrome, (which may include hypercalcaemia and alkalosis) or constipation or renal dysfunction may occur at high dosages.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium carbonate functions as an antacid reacting with excess hydrochloric acid in the gastric medium to produce a soluble chloride.



5.2 Pharmacokinetic properties

A small amount of calcium may be absorbed, but in healthy subjects it is usually rapidly excreted by the kidney. The soluble chloride produced by the reaction of calcium with gastric acid reacts, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3 Preclinical safety data

No additional data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Potato starch
Pregelatinised maize starch
Magnesium stearate
Talc
Citric acid anhydrous
Orange flavour
Quinoline yellow (E104)
Ponceau 4R (E124)
Saccharin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Tablets are packed in clear styrolex bottles with polypropylene lids, containing 30, 70, 100, or 150 tablets.

Alternatively, 8 tablets are roll wrapped in laminated foil.

Alternatively, tablets are packed in aluminium foil/pvc blister strips with 4, 8, or 12 tablets per strip.

1, 2, 3, 4, 6, 8, 10, or 12 strips are placed in a cardboard carton. (8, 12, 24, 32, 48, 60, 64, 72, 80, 96, or 120 tablets per carton), which may contain one or more cut-out "windows".

Alternatively one strip of 8 tablets is presented in a cardboard sample wallet which may contain one or more cut-out "windows".

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury
Berkshire RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 21/78/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 1991

Date of last renewal: 22 August 2006

10 DATE OF REVISION OF THE TEXT

March 2007